The shape of things to come

Coming Soon from GlaxoSmithKline

Pediarix™

Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined
Now approved in patients as young as 6 years...

- **Proven safe and effective at a new lower dose…**
  
  Xopenex® 0.31 mg

  - From one of the largest, well-controlled, pediatric trials conducted with a β-agonist

  - Now available in two doses, 0.31 mg and 0.63 mg, for children ages 6-11 years

- **Devoid of the unnecessary left isomer, (S)-albuterol**

In patients aged 6 to 11 years, the adverse events occurring in ≥2% of patients and more frequently than with patients receiving placebo, were (0.31 mg Xopenex; 0.63 mg Xopenex; and placebo, respectively): headache (7.9%; 11.9%; 8.5%), pharyngitis (5.3%; 9.4%; 0.8%), rhinitis (6.1%; 10.4%; 1.7%), asthma (3.1%; 9.0%; 5.1%), fever (1.9%; 9.0%; 3.1%), viral infection (76%; 94%; 3.1%), rash (MA*: 75%; NA*), accidental injury (6.2%; 4.1%; 2.7%), diarrhea (1.5%; 6.7%; NA*), pain (3.0%; 1.5%; 3.4%), asthenia (NA*; 3.0%; NA*), lymphadenopathy (NA*; NA*; NA*), and urticaria (NA*; 9.6%; NA*).

In patients aged 12 years and older, the adverse events occurring in ≥2% of patients and more frequently than with patients receiving placebo, were (0.63 mg Xopenex; 1.25 mg Xopenex; and placebo, respectively): viral infection (6.9%; 12.3%; 0.8%), rhinitis (11.3%; 2.7%; 2.7%), nervousness (2.8%; 0.8%; NA*), fever (MA*: 0.8%; NA*; NA*; nasal congestion (4.2%; 1.4%; 2.7%), tachycardia (4.2%; 1.4%; NA*), pain (2.8%; 1.4%; 1.9%), turbinate edema (2.8%; 1.4%; NA*), dizziness (1.4%; 2.7%; 1.3%), dysgeusia (1.4%; 2.7%; 1.3%), leg cramps (NA*; 2.7%; 1.3%), accidental injury (NA*; 2.7%; 1.3%), anxiety (NA*; 2.7%; NA*), and migraine (NA*; 2.7%; NA*).

*Less than 2% reported.

Xopenex is contraindicated in patients with a history of hypersensitivity to levalbuterol HCl or racemic albuterol.

See next page for brief summary of Xopenex prescribing information and safety information concerning β-agonists.


SRP989  07/02
New
Once-daily
Ritalin® LA
The ADHD original.
Optimized
for the school day.

- Rapid onset of Ritalin®
- Mimics bid dosing
- Lasts the school day
- Favorable safety and
tolerability in clinical trials¹
- Flexible, once-daily dosing
  - Capsules offer sprinkle option
  - Available in three dosage strengths


Ritalin® LA is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Ritalin® LA should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence. Frank psychotic episodes can occur, especially with parenteral abuse. (See Boxed Warning.)

Please see brief summary of full prescribing information, including Contraindications and Boxed Warning, provided on the following page.

Due to Staphylococcus aureus and Pseudomonas aeruginosa in patients ≥1 year of age

† Based on total prescriptions from IMS National Weekly Prescription Audit, 52 weeks ending 12/01
Please see brief summary below.

FLOXIN® Otic (ofloxacin otic solution) 0.3%
Brief Summary: Please see product insert for complete prescribing information.
For otic use only.

INDICATIONS AND USAGE
FLOXIN® Otic (ofloxacin otic solution) 0.3% is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

*Otitis Externa in adults and pediatric patients, one year and older due to Staphylococcus aureus and Pseudomonas aeruginosa.
*Chronic Suppurative Otitis Media in patients 12 years and older with perforated tympanic membranes due to Staphylococcus aureus, Proteus mirabilis, and Pseudomonas aeruginosa.
*Acute Otitis Media in pediatric patients one year and older with tympanosotomy tubes due to Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, and Pseudomonas aeruginosa.

CONTRAINDICATIONS
FLOXIN® Otic (ofloxacin otic solution) 0.3% is contraindicated in patients with a history of hypersensitivity to ofloxacin, to other quinolones, or to any of the components of this medication.

WARNINGS
NOT FOR OROPHARYNGEAL USE.
NOT FOR INJECTION.
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones, including ofloxacin. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal), pharyngitis, or facial edema, airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to ofloxacin is suspected, stop the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management, including intubation, should be administered as clinically indicated.

PRECAUTIONS
General: As with other anti-infective preparations, prolonged use may result in overgrowth of nonsusceptible organisms including fungi. If the infection is not improved after one week, cultures should be obtained to guide further treatment. If otitis persists after a full course of therapy, or if two or more episodes of otitis occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumor.

The systemic administration of quinolones, including ofloxacin at doses much higher than those given or absorbed by the otic route, has led to lesions or erosions of the nasal erectile tissue in weight-bearing joints and other signs of arthropathy in immature animals of various species.

Young growing pigs dosed in the middle ear with 0.3% ofloxacin otic solution showed no systemic effects, lesions or erosions of the cartilage in weight-bearing joints, or other signs of arthropathy in immature animals of various species.

Information for Patients: Avoid contaminating the applicator tip with material from the fingers or other sources. This precaution is necessary because the fluid of the drops is to be preserved. Systemic quinolones, including ofloxacin, have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

*Otitis Externa
Prior to administration of FLOXIN® Otic in patients with otitis externa, the solution should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, and then the drops should be instilled. This position should be maintained for five minutes to facilitate penetration of the drops into the middle ear. If necessary, for the opposite ear (see DOSAGE AND ADMINISTRATION).

*Acute Otitis Media and Chronic Suppurative Otitis Media
In pediatric patients (from 1 to 12 years old) with acute otitis media with tympanosotomy tubes and in patients with chronic suppurative otitis media with perforated tympanic membranes, prior to administration, the solution should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, and then the drops should be instilled. The whole should be pumped 4 times by pushing inward to facilitate penetration of the drops into the middle ear. This position should be maintained for five minutes. Repeat, if necessary, for the opposite ear (see DOSAGE AND ADMINISTRATION).

Drug Interactions: Specific drug interaction studies have not been conducted with FLOXIN® Otic.

Carbenicillin, Metronidazole, Imipenem/Cilastatin
Long-term studies to determine the carcinogenic potential of ofloxacin have not been conducted. Ofloxacin was not mutagenic in the Ames test, the sister chromatid exchange assay (Chinese hamster and human cell lines), the unscheduled DNA synthesis (UDS) assay using human fibroblasts, the dominant lethal assay, or the mouse micro-nuclear assay. Ofloxacin was positive in the rat hepatocyte UDS assay and in the mouse lymphoma assay. In rats, ofloxacin did not affect male or female reproductive performance at oral doses up to 500 mg/kg/day. This would be over 1000 times the maximum recommended clinical dose, based upon body surface area, assuming total absorption of ofloxacin from the ear of a patient treated with FLOXIN® Otic twice per day.

Pregnancy
Teratogenic effects: Pregnancy Category C. Ofloxacin has been shown to have an embryocidal effect in rats at a dose of 810 mg/kg/day and in rabbits at 160 mg/kg/day. These dosages resulted in decreased fetal body weights and increased fetal mortality in rats and rabbits, respectively. Minor fetal anatomic variations were reported in rats receiving doses of 810 mg/kg/day. Ofloxacin has not been shown to be teratogenic at doses as high as 810 mg/kg/day and 160 mg/kg/day when administered to pregnant rats and rabbits, respectively.

Ofloxacin has not been shown to have any adverse effects on the developing embryo or fetus at doses relevant to the amount of ofloxacin that will be delivered systemically at the recommended clinical dose.

Nonteratogenic Effects: Additional studies in the rat demonstrated that doses up to 360 mg/kg/day during late gestation had no adverse effects on late fetal development, labor, delivery, lactation, neonatal viability, or growth of the newborn. There are, however, no adequate and well-controlled studies in pregnant women. FLOXIN® Otic should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: In nursing women, a single 200 mg oral dose resulted in concentrations of ofloxacin in milk which were similar to those found in plasma. It is not known whether ofloxacin is excreted in human milk following topical otic administration. Because of the potential for serious adverse reactions from ofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: No changes in hearing function occurred in 30 pediatric subjects treated with ofloxacin otic and tested for audiometric parameters. Although safety and efficacy have been demonstrated in pediatric patients one year and
Power to relieve pain as fast as Cortisporin™ otic solution™, but without a steroid.

**Power against otitis externa due to Staphylococcus aureus and Pseudomonas aeruginosa in patients ≥1 year of age**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Clinical cure rate</th>
<th>Percentage of clinical cure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>93%</td>
<td></td>
</tr>
</tbody>
</table>

**Safe and well-tolerated topical power**

**Safety information**

Most commonly reported adverse reactions in clinical trials in otitis externa patients treated twice daily with FLOXIN® Otic (n=229): pruritus (4%), application site reaction (3%), dizziness (1%), earache (1%), and vertigo (1%).

FLOXIN Otic is contraindicated in patients with a history of hypersensitivity to ofloxacin, other quinolones, or other ingredients of the medication, and should be discontinued at the first sign of allergic reaction. Patients who have not improved after 1 week of treatment should be evaluated by their doctor.

Safety and efficacy have not been established in patients <1 year of age with otitis externa.

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**ADVERSE REACTIONS**

In the Phase II registration trials, a total of 485 subjects were treated with ofloxacin otic solution. This included 229 subjects with otitis externa (with intact tympanic membranes) and 266 subjects with acute otitis media with tympanostomy tubes or chronic supplicative otitis media with perforated tympanic membranes. The reported treatment-related adverse events are listed below.

**Subjects with Otitis Externa**

The following treatment-related adverse events occurred in 1% or more of the subjects with intact tympanic membranes.

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Frequency (n = 229)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pruritus</td>
<td>4%</td>
</tr>
<tr>
<td>Application Site Reaction</td>
<td>3%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1%</td>
</tr>
<tr>
<td>Earache</td>
<td>1%</td>
</tr>
<tr>
<td>Vertigo</td>
<td>1%</td>
</tr>
</tbody>
</table>

The following treatment-related adverse events were each reported in a single subject: dermatitis, eczema, erythema-tous rash, follicular rash, rash, hypoaesthesia, tinnitus, dry eyes, hot flashes, flushing, and otitis media.

**Subjects with Acute Otitis Media with Tympanostomy Tubes and Subjects with Chronic Suppurative Otitis Media with Perforated Tympanic Membranes**

The following treatment-related adverse events occurred in 1% or more of the subjects with non-intact tympanic membranes.

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Frequency (n = 266)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taste Perversion</td>
<td>7%</td>
</tr>
<tr>
<td>Earache</td>
<td>1%</td>
</tr>
<tr>
<td>Pruritus</td>
<td>1%</td>
</tr>
<tr>
<td>Paroxysm</td>
<td>1%</td>
</tr>
<tr>
<td>Rash</td>
<td>1%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1%</td>
</tr>
</tbody>
</table>

Other treatment-related adverse reactions reported in subjects with non-intact tympanic membranes included: diarrhea (5%), nausea (3%), vomiting (3%), dry mouth (5%), headache (3%), vertigo (3%), tachycardia (3%), bronchitis (3%), fever (3%), rhinitis (3%).

**DOSEAGE AND ADMINISTRATION**

**Otitis Externa**

The recommended dosage regimen for the treatment of otitis externa is: For pediatric patients (from 1 to 12 years old): Five drops (0.25 mL, 0.75 mg ofloxacin) instilled into the affected ear twice daily for ten days. For patients 12 years or older: Ten drops (0.5 mL, 1.5 mg ofloxacin) instilled into the affected ear twice daily for ten days. The solution should be warmed by holding the bottle in the hand for one to two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should be with the affected ear upward, and then the drops should be instilled. This position should be maintained for five minutes to facilitate penetration of the drops into the ear canal. Repeat, if necessary, for the opposite ear.

**Acute Otitis Media**

For the treatment of chronic suppurative otitis media with perforated tympanic membranes in patients 12 years or older:

Ten drops (0.5 mL, 1.5 mg ofloxacin) instilled into the affected ear twice daily for fourteen days. The solution should be warmed by holding the bottle in the hand for one to two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should be with the affected ear upward, before instilling the drops. This position should be maintained for five minutes. Repeat, if necessary, for the opposite ear.

**References**

2. Based on overall responses of twice-daily ofloxacin-treated patients in Phase III clinical trials (INO-279).

**Ortho-Neilen**

Ortico Pharmaceutical Corporation
Montvale, NJ 07645
(913) 303-0482

(FAS April 20, 1998)

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ELIDEL is contraindicated in patients who are hypersensitive to pimecrolimus or any of the components of the cream. It should not be applied to areas of active cutaneous infections. Use should be carefully evaluated if varicella zoster virus, herpes simplex virus, or eczema herpeticum infections are present.

If patients have lymphadenopathy that is unresolved or of unclear etiology, discontinuation should be considered. Patients should minimize or avoid natural or artificial sunlight exposure. **ELIDEL should not be used with occlusive dressings.**

The most common adverse events seen in clinical studies included application-site burning, headache, pharyngitis, nasopharyngitis, cough, influenza, pyrexia, and viral infection. In clinical studies, skin papilloma or warts were observed in 1% of ELIDEL patients. The efficacy and safety of ELIDEL have not been studied beyond 1 year.
When you want or need to avoid corticosteroids for your mild to moderate eczema patients*

**ELIDEL® in control.**

- Effectively relieves the itch, redness, inflammation, and excoriation of eczema flares
- Significantly improved the pruritus that caused sleep disturbance by first visit (Day 8), and through endpoint of a 6-week study ($P<0.001$)**
- Proven safe and well tolerated in patients aged 2 years through adult
- In a safety study, 57% of pediatric ELIDEL patients had no flares requiring a corticosteroid over 1 year§
- Odor-free, easy-to-use cream that may be used on any skin surface
- Should be used twice daily at the earliest signs or symptoms and for as long as they persist*†

**ELIDEL is indicated for short-term and intermittent long-term therapy for mild to moderate atopic dermatitis in non-immunocompromised patients 2 years of age and older, in whom the use of alternative, conventional therapies is deemed inadvisable because of potential risks, inadequate clinical response, or patient intolerance of such therapies.

Pruritus was assessed on a 4-point scale as 0 (none), 1 (occasional/slight itching), 2 (constant or intermittent itching which does not disturb sleep), and 3 (bothersome itching which disturbs sleep).

Data from the 6-week, double-blind phases of two, 26-week, multicenter trials comparing ELIDEL to placebo cream in pediatric patients with mild to moderate eczema aged 2 to 17 years (n=403).

Data from a 1-year, randomized, multicenter, double-blind, placebo-controlled study in patients aged 2 to 17 years. An increased incidence of skin infections, rhinitis, and urticaria was found in patients using ELIDEL sequentially with topical corticosteroids as compared to ELIDEL alone.

Intermittent therapy with ELIDEL has been studied up to 1 year. Treatment should be discontinued upon resolution of disease. Patients should be re-evaluated if symptoms persist beyond 6 weeks.

Please see brief summary of Prescribing Information.
In the treatment of the nasal symptoms of allergic rhinitis with nasal inhaled steroids

ONE POWERFUL CHOICE
COVERS THEM ALL

NEW INDICATION

- The only nasal steroid indicated in patients as young as 2 years of age
- Studied in geriatrics up to age 85
- Proven efficacy and safety profile for all ages in between

WARNING: The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency.

In clinical trials, using the recommended dose, the overall incidence of adverse events was comparable to vehicle placebo. The most commonly reported adverse events, not necessarily drug related, were, for NASONEX® and vehicle placebo, respectively: headache (17.26% vs 18.22%), viral infection (8.14% vs 9.11%), pharyngitis (10.12% vs 10%), epistaxis/blood-tinged mucus (8.11% vs 6.9%), and coughing (7.13% vs 6.15%).

WWW.NASONEX.COM

For more information, please see your Schering representative.

Please see accompanying brief summary of Prescribing Information on adjacent page.
NASONEX®
(mometasone furoate monohydrate)
Nasal Spray, 50 mcg per spray
FOR INTRanasAL USE ONLY
(calculated on the antihistamine basis)

BRIFE PRODUCT INFORMATION
See Package Insert. See precautions. See indications & usage. For intranasal use only. See precautions. See indications & usage.

INDICATIONS AND USAGE NASONEX Nasal Spray, 50 mcg is indicated for the treatment of the nasal symptoms of seasonal and nonseasonal allergic rhinitis in adult and adolescent patients 12 years of age and older. NASONEX Nasal Spray, 50 mcg is indicated for the prophylaxis of the symptoms of seasonal allergic rhinitis in adult and adolescent patients 12 years of age and older. NASONEX Nasal Spray, 50 mcg is indicated for the treatment of the symptoms of seasonal allergic rhinitis, initiation of prophylaxis with NASONEX Nasal Spray, 50 mcg is indicated (see Indications & Usage). See contraindications for intranasal use. See precautions.

NASONEX Nasal Spray, 50 mcg is indicated for the treatment of the symptoms of seasonal allergic rhinitis in adults and adolescents 12 years of age and older. NASONEX Nasal Spray, 50 mcg is indicated for the prevention of the symptoms of seasonal allergic rhinitis in patients 6 to 11 years of age on a steroid-naive basis. NASONEX Nasal Spray, 50 mcg is indicated for patients less than 3 years of age have not been established.

CONTRAINDICATIONS Hyperesthesia to any of the ingredients of this preparation contraindicates its use.

WARNINGS The replacement of a systemic corticosteroid with a topical corticosteroid is accompanied by signs of adrenal insufficiency and, in addition, some patients may experience symptoms of withdrawal, i.e., lack of energy, depression, fatigue, insomnia, and malaise. To avoid such symptoms, patients who are on prolonged periods with systemic corticosteroids are transferred to topical corticosteroids, with careful monitoring of adrenal insufficiency in response to stress. This is particularly important in those patients who have associated asthma or other clinical conditions where too rapid a decrease in systemic corticosteroid dosing may cause adrenal insufficiency.

If recommended doses of intranasal corticosteroids are exceeded or if individuals are particularly sensitive or predisposed to patients with a recent history of a history of systemic disease or asthma, including very rare cases of nasal ulcerations, eosinophils, and nasal septum perforation. If such changes occur, topical corticosteroids should be discontinued promptly. See precautions for prolonged use.

Persons who are on drugs which suppress the immune system may be more susceptible to infections than healthy individuals. Chickenpox, measles, or chickenpox-like symptoms, chickenpox, or chickenpox-like symptoms, or chickenpox-like symptoms. This is particularly important in those patients who have associated asthma or other clinical conditions where too rapid a decrease in systemic corticosteroid dosing may cause adrenal insufficiency.

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Focalin™ is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Focalin™ should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. (See Boxed Warning.)